REMARKS

In reply to the Office Action dated April 21, 2005, reconsideration is respectfully requested in view of the above amendments and the following remarks. Claims 2-5 and 13 are currently under examination in the Application. By the above amendment, claims 2-5 and 13 have been canceled and new claims 14-16 have been added. The above amendments are not to be construed as acquiescence to the stated grounds for objection/rejection and are made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

Claims Rejections Under 35 U.S.C. § 112, first paragraph

Claims 2-5 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicants, at the time the application was filed, had possession of the claimed invention. According to the Examiner, the application as filed does not adequately support the limitation wherein the claimed polypeptide consists of *no more than* amino acid residues 975-1209 of human Her-2/neu.

Applicants respectfully traverse this rejection and submit that the claimed subject matter is more than adequately enabled under 35 U.S.C. § 112, first paragraph. Without acquiescing to the stated grounds for rejection, however, Applicants submit herewith new claims 14-16, drawn to isolated polypeptides *consisting of* residues 975-1209 of SEQ ID NO: 2 or a portion of said polypeptide *consisting of* at least residues 1021-1030 (SEQ ID NO: 3). Applicants further submit that such subject matter is fully described and supported by the specification as originally filed.

As set forth in Example 2, Applicants identified a T-cell immunogenic fragment of human Her-2/neu corresponding to a 235 amino acid fragment from residues 975-1209 of Her-2/neu. Furthermore, using gamma interferon release and TNF-alpha release assays, the sequence of a naturally processed Her-2/neu T cell epitope was identified within the 235 amino acid immunogenic fragment as having the sequence EEYLVPQQGF (SEQ ID NO: 3), corresponding to residues 1021-1030 in the Her-2/neu protein sequence of SEQ ID NO: 2. In view of this disclosure, a skilled artisan would understand and appreciate that Applicants had

identified, described, and were in possession of, the claimed polypeptides consisting of residues 975-1209 of SEQ ID NO: 2 or a portion of said polypeptide consisting of at least residues 1021-1030 (SEQ ID NO: 3). Such understanding is further strengthened by Applicants' disclosure that a polypeptide of the invention may be an entire protein, or a subsequence thereof. Particular polypeptides of interest are described as amino acid subsequences comprising epitopes, *i.e.* antigenic determinants substantially responsible for the immunogenic properties of a polypeptide and being capable of evoking an immune response (page 9, lines 24-28). In addition, the specification describes that particularly preferred polypeptide compositions are from the ICD region of the Her-2/neu protein, preferably containing some or all of the region from about amino acids 676-1255 of SEQ ID NO: 2, and more preferably comprising at least the naturally processed HLA-B44-restricted Her-2/neu epitope set forth in SEQ ID NO: 3 (page 10, lines 16-19).

In light of the above, it is respectfully submitted that the specification describes and conveys clearly and unambiguously Applicants' possession of the polypeptides presently claimed, consisting of residues 975-1209 of SEQ ID NO: 2 or portions thereof consisting of at least residues 1021-1030. Reconsideration of this rejection is respectfully requested.

New Rejections Under 35 U.S.C. § 112, first paragraph

Claims 3-5 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More particularly, the Examiner asserts that one cannot extrapolate the teachings of the specification to the enablement of the claims because allegedly implicit in the recitation of a pharmaceutical composition is the *in vivo* use thereof for treatment.

Applicants respectfully traverse this rejection and submit that the claimed invention is indeed fully enabled by the specification as originally filed. Applicants further submit that the claimed invention is drawn to compositions, not therapeutic methods, and that it is not required that *in vivo* therapeutic efficacy be established and demonstrated in order to satisfy the enablement requirements under 35 U.S.C. § 112, first paragraph. Nevertheless, in an effort to advance prosecution of the subject application, but without prejudice to further

prosecution in a related application, claims drawn to "pharmaceutical compositions" have been removed at this time.

Claims 2-5 and 13 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicants, at the time the application was filed, had possession of the claimed invention. More particularly, according to the Examiner, the claims encompass polypeptides which vary substantially in length and also in polypeptide composition, and are not limited to an immune response to SEQ ID NO: 3 but read on an immune response to any undefined polypeptide to which SEQ ID NO: 3 is attached. The Examiner further notes that the rejection may be obviated by use of "consisting of" language.

Applicants respectfully traverse this rejection and submit that the specification as originally filed would more than adequately lead a skilled artisan to appreciate that Applicants were in possession of the subject matter claimed. However, in the interest of advancing prosecution of the subject application to allowance, the currently pending claims have been amended to recite a polypeptide consisting of residues 975-1209 of SEQ ID NO: 2 or a portion of said polypeptide consisting of at least residues 1021-1030 (SEQ ID NO: 3). As Applicants have identified an immunogenic fragment corresponding to claimed residues 975-1209 of Her-2/neu, and have further identified the T cell epitope contained within that fragment and corresponding to claimed residues 1021-1030, it is respectfully submitted that the subject matter as currently claimed was well within Applicants' possession at the time of filing and would be recognized as such by an artisan of ordinary skill. Reconsideration is respectfully requested.

New Rejections Under 35 U.S.C. § 102

Claims 2-5, and 13 stand rejected as allegedly being anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 5,869,445. According to the Examiner, U.S. Patent No. 5,869,445 describes a human Her-2/neu sequence comprising SEQ ID NO: 2 and claims a method for eliciting or enhancing an immune response to Her-2/neu protein comprising administering to a human a polypeptide having the amino acid sequence of SEQ ID NO: 2 from amino acid 676 to amino acid 1255, and further teaches that DC cultures were incubated with human Her-2/neu and then incubated with naïve CD4+ T lymphocytes. The Examiner concludes that "it would be

expected that at least a subset of the incubated dendritic cells comprise the claimed amino acid sequences," and apparently rejects Applicants' claims to isolated polypeptides on this basis.

Applicants respectfully traverse. Applicants have identified and claimed an isolated polypeptide consisting of a specific immunogenic fragment of Her-2/neu, and have identified the presence and location of a naturally processed T-cell epitope contained within the fragment. U.S. Patent No. 5,869,445 does not anticipate Applicants' claimed polypeptides consisting of residues 975-1209 of SEQ ID NO: 2 or a portion of said polypeptide consisting of at least residues 1021-1030 (SEQ ID NO: 3), because the reference does not teach or suggest a polypeptide meeting the elements of Applicants' claims. Dendritic cells (DCs) incubated in the presence of human Her-2/neu protein, as described by the reference, do not anticipate isolated polypeptides as currently claimed. Further, it does not follow from the description of an experiment in which DCs are incubated with a Her-2/neu polypeptide that the cited reference has somehow described with particularity an isolated polypeptide fragment as specifically claimed by Applicants. The cited reference describes incubated dendritic cells, not isolated polypeptides, and such disclosure cannot fairly or reasonably be viewed as anticipatory with respect to the present claims when the elements of the claims are lacking from the reference. Reconsideration is respectfully requested.

Claims 2-5 and 13 stand rejected as allegedly being anticipated under 35 U.S.C. § 102(e) over US 2002/0177567. More particularly, the Examiner asserts that the cited reference teaches a polypeptide comprising a 59 amino acid fragment of human Her-2/neu, SEQ ID NO: 5, which allegedly has 100% identity to a portion of instant SEQ ID NO: 2, within the claimed range which comprises SEQ ID NO: 3. According to the Examiner, due to the use of "comprising" language, the instant claims are anticipated by the description of fusion polypeptides in the cited reference.

Applicants respectfully traverse this rejection. US 2002/0177567 does not teach an isolated polypeptide consisting of residues 975-1209 of SEQ ID NO: 2 or a portion of said polypeptide consisting of at least residues 1021-1030, as currently claimed by Applicants. Rather, the cited reference describes that a polypeptide referred to as SEQ ID NO: 5 is used in fusion with a separate and distinct polypeptide, but does not describe its use alone as an isolated

polypeptide by itself. The cited reference does not anticipate Applicants' claimed isolated polypeptide consisting of residues 975-1209 of SEQ ID NO: 2 or a portion thereof consisting of at least residues 1021-1030, as the reference explicitly describes that the disclosed SEQ ID NO: 5 be used in fusion with another polypeptide. Reconsideration is respectfully requested.

Obviousness-Type Double Patenting

Claim 13 stands rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 and 2 of U.S. Patent No. 6,075,122. This rejection appears predicated on the Examiner's interpretation of the transitional phrase, "consisting essentially of." More particularly, the Examiner is of the view that "it is clear that the claims read on the full length sequence of human Her-2/neu comprising SEQ ID NO: 3 as well as subsequence of human Her-2/neu comprising SEQ ID NO: 3 because neither the full sequence nor the subsequence will affect the basic and novel characteristic, that is the characteristic of being an immunogenic polypeptide which is a naturally processed T-cell epitope. The Examiner concludes that it would have been obvious to one of skill in the art in view of the claims of the cited reference to have made a polypeptide composition according to Applicants' claims, said polypeptide consisting essentially of SEQ ID NO: 3, given that U.S. Patent No. 6,075,122 expressly contemplates immunogenic compositions and the specification allegedly teaches a vaccine comprising a polypeptide consisting of SEQ ID NO: 69, amino acid residues 676-1255 of instant SEQ ID NO: 2.

Applicants respectfully traverse this rejection and submit that currently claimed subject matter is patentably non-obvious over the claims of U.S. Patent No. 6,075,122. As set forth by the above amendment, the claimed invention is drawn to an isolated polypeptide consisting of residues 975-1209 of SEQ ID NO: 2 or a portion of said polypeptide consisting of at least residues 1021-1030. The cited reference, however, fails to teach, suggest, or otherwise render obvious this claimed invention, as this cited art does not fairly teach or suggest the elements claimed. More specifically, U.S. Patent No. 6,075,122 fails to render obvious the claimed Her-2/neu polypeptides consisting of amino acid residues 975-1209 of human Her-2/neu protein or a fragment thereof consisting of at least residues 1021-1030 of human Her-2/neu, because U.S. Patent No. 6,075,122 does not describe that a polypeptide consisting of amino acid

residues 975-1209 of human Her-2/neu is a T-cell immunogenic fragment, or that amino acid residues 1021-1030 correspond to an important naturally processed T cell epitope within the immunogenic fragment. Accordingly, as the cited claims 1 and 2 fail to teach, suggest, or otherwise lead a skilled artisan to the specific Her-2/neu polypeptides now claimed, Applicants respectfully request reconsideration of the Examiner's double patenting rejection.

Claims Rejections Under 35 U.S.C. § 112, second paragraph

Claims 2-5 and 13 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. According to the Examiner, claims 2-5 are indefinite because claim 2 recites the phrase "no more than amino acid residues 975-1209 of human Her-2/neu" without providing a frame of reference to a specific Her-2/neu sequence claimed.

Applicants respectfully traverse this rejection on the basis that a skilled artisan would understand and appreciate, in view of Applicants' specification, the metes and bounds of the claimed invention. Nevertheless, in the interest of advancing prosecution of the subject application, the currently pending claims now make specific reference to the human Her-2/neu sequence disclosed by Applicants as SEQ ID NO: 2, as suggested by the Examiner.

Claims 2-5 and 13 also stand rejected as being allegedly indefinite because the phrase "effective for eliciting an immune response" is not specific to eliciting an immune response against the specifically claimed Her-2/neu sequences. Applicants respectfully traverse this rejection, however, for purposes of expediting prosecution, and without prejudice to further prosecution in a related application, Applicants have removed reference to the phrase "eliciting an immune response" in the pending claims, thereby rendering the Examiner's rejection moot. Reconsideration of this rejection is respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now believed to be in condition for allowance. Favorable consideration is respectfully requested.

Respectfully submitted,

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